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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/455,683	BELL ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *53-58,60-62,68-80,97-102,109,112-114,123 and 137-143* is/are pending in the application.

4a) Of the above claim(s) *53-58,60-62 and 68-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97-102,109,112-114,123 and 137-143* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A FINAL Office Action was mailed 8/19/02 (Paper No. 40). However, upon further consideration by the Examiner, the finality of that action is withdrawn and prosecution on the merits continues.

1. Formal Matters

A. Claims 53-58, 60-62, 68-80, 97-102, 109, 112-114, 123 and 137-143 are pending. Claims 53-58, 60-62, 68-80 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 97-102, 109, 112-114, 123 and 137-143 are the subject of this Office Action.

B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 97-102 remain rejected for the reasons already of record on pages 2-3 of the Office Action dated 8/19/02. Due to the fact that the approximately 300 known residues of the protein encoded for by SEQ ID NO:11 are 95% identical to the homologous portion of the fully characterized mouse kappa opioid receptor encoded for by SEQ ID NO:1, and the fact that the second extracellular loop of each of these receptors is 100% identical, the rejection of claims 109, 112-114, 123 and 137-143 under 35 USC 112, first paragraph, has been withdrawn.

Applicants argue that the claims at issue pertain to processes for screening and processes for isolating substances for their ability to interact with an opioid receptor utilizing recombinant opioid receptor polypeptides encoding at least 30 contiguous bases of SEQ ID NO:11, which is a partial genomic sequence of a human opioid receptor. Applicants argue that the Examiner has the initial burden of presenting evidence why one of skill in the art would not recognize in Applicants' disclosure a description defined in the claims and to provide reasons why the artisan would not have recognized the description of the limitation in view of Applicants' disclosure. Applicants argue that they are not required to disclose the full-length receptor in order to provide written description support for their claims. Applicants argue that the process pertains to fragments of SEQ ID NO:11 and that the full-length protein is not required to practice the claimed invention.

These arguments have been considered, but are not deemed persuasive. Claim 97, as written, recites a process for screening a substance for its ability to specifically bind to an opioid receptor wherein the receptor comprises at least 30 contiguous bases of SEQ ID NO:11. However, claim 97 does not recite that the opioid receptor polypeptide must comprise any of the known regions (e.g. second extracellular loop) required for binding. Applicants previously argued in the Response filed 6/5/00 that the claims do not require "ligand binding" and that the claims are directed to "processes for screening a substance for its ability to interact with an opioid receptor." Applicants also argued that the Sequence Listing contains SEQ ID NO:11 and, therefore, shows "which groups of 30 nucleotides o[f] SEQ ID NO:11 will translate into a functional opioid polypeptide that can bind ligands. Though the Sequence Listing does give the nucleotide and translated amino acid sequences, the Listing does not allow one to determine which groups of 30 nucleotides are able to bind the genus of compounds which are encompassed by these claims. Applicants have only provided adequate written description of regions such as the second extracellular loop and the claims read on screening for agonists and antagonists. Without further describing in the claims the regions required for the binding of compounds other than ligands, or without limiting the claims to recite a method of screening for antibodies only, this rejection is maintained.

Applicants argument in the Appeal Brief, filed 3/28/03, that "any claim to a polypeptide comprising a particular newly discovered amino acid sequence wherein the amino acid sequence is fully disclosed in the specification could never be claimed since it is possible that the amino acid sequence might at some later point in time be attached to an object that is not presently disclosed in the specification" is incorrect. Numerous proteins are known to form dimers and it is well-known that fusion proteins can be produced using proteins, or the encoding polynucleotides. These "attachments" to the molecules of the specification would have written description if disclosed in the specification. The issue is not that all "attachments" have to be described. Applicants are implying that attaching items to a protein, such as making fusion proteins, for example, is analogous to adding polynucleotides or amino acids to a molecule to make it full-length. The issue here is not that items can't be attached to the polynucleotide of the present invention, but that the basic molecule for which attachment is necessary, is the full-length protein. Without having a start and stop codon, this polynucleotide, for example, would read on an entire gene, which is not described.

In fact, "vertebrate insulin cDNA," as argued by Applicants, is similar to "kappa opioid receptors encoded by SEQ ID NO:11" since these are, in a matter of speaking, generic statements. Neither of these terms has been adequately described to allow the artisan to identify the molecules of these genii. An artisan could no more describe any full-length proteins comprising SEQ ID NO:11 than he could describe

a full-length vertebrate insulin cDNA. In fact, unlike the kappa opioid receptor comprising SEQ ID NO:11, the structure of numerous vertebrate insulin cDNAs are well-known in the art. Therefore, in some respects, insulin cDNAs are more adequately described than are kappa opioid receptors comprising SEQ ID NO:11, since only a fragment of this receptor is described. While it is true that Applicants do not need to describe every embodiment on which the claim reads, they do need to describe the full-length receptor since these claims are currently "reach through" claims. Applicants are attempting to receive patent protection on the full-length kappa opioid receptor even though they are not in possession of this receptor. In fact, without being in possession of the full-length receptor, it is not known how Applicants can accurately determine that a compound is an agonist, or an antagonist of the receptor, as the present invention claims. It is believed that all pertinent arguments have been addressed.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 97-102 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for a process of screening for antibodies, does not reasonably provide enablement for a process of screening for agonists, antagonists, or any other compounds which are known to require specific regions of the human kappa opioid receptor for binding or activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to Applicants claiming a screening method using any and all portions of SEQ ID NO:11 which comprise at least 30 contiguous bases of SEQ ID NO:11. Applicants have only provided guidance and working examples of proteins of SEQ ID NO:2, which is 95% identical to SEQ ID NO:12 over the 300 known residues of SEQ ID NO:12, wherein the protein comprises the second extracellular loop of SEQ ID NO:12 (which is 100% identical to that of SEQ ID NO:2). The scope of the claims reads on compounds other than antibodies. However, claim 97 does not require that the protein comprise any known amino acid regions required for the binding and/or function of ligands other than antibodies. Therefore, without the recitation of the second extracellular

loop, or other known regions disclosed as being required for binding of compounds other than antibodies, Applicants are only enabled for the screening method of claim 97 which is only used to screen antibodies. Without guidance or working examples of what residues are required in this claimed method, it is not predictable to the artisan as to what residues would be required to practice the invention of claim 97. The recitation of "at least 30 contiguous bases" is not sufficient guidance to allow the artisan to practice the invention as claimed.

In summary, the breadth of the claims is excessive with regard to Applicants claiming a screening method for any compounds other than antibodies. There is no guidance or working examples of screening methods which do not use the second extracellular loop of the protein, nor would it be predictable to the artisan which residues would be required to permit the binding of ligands other than antibodies to the receptor. For these reasons, the Examiner holds that undue experimentation is required to practice the invention as claimed.

4. Claim Rejections - 35 USC § 112, second paragraph

Claims 109, 112-114, 123 and 137-143 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 109 and 112-114 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method steps for isolating the claimed substance. As written, it is not clear how to substance is to be isolated.

B. Claims 109, 112-114, 123 and 137-143 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a method step(s) for determining that the isolated substance is an agonist. No functional tests have been recited in the methods. Applicants are claiming a method of identifying a substance as an agonists simply by identifying its ability to bind a receptor. Binding is not necessarily indicative of functional ability.

5. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
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June 16, 2003

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